

# **CLIA C - November 2018**

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Director, Division of Laboratory Services  
Centers for Medicare & Medicaid Services

# Personnel Changes

**Karen Tritz,**  
Acting Director, QSOG

**Tennille Rogers**  
Deputy Director, QSOG

# Current Statistics--Enrollment

<b><u>Total Number of Laboratories</u></b>	<b><u>261,979</u></b>
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<b><u>Total Non-Exempt</u></b>	<b><u>252,567</u></b>
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<u>Compliance</u>	17,807
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<u>Accredited</u>	15,867
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<u>Waived</u>	187,403
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<u>Provider Performed Microscopy</u>	31,490
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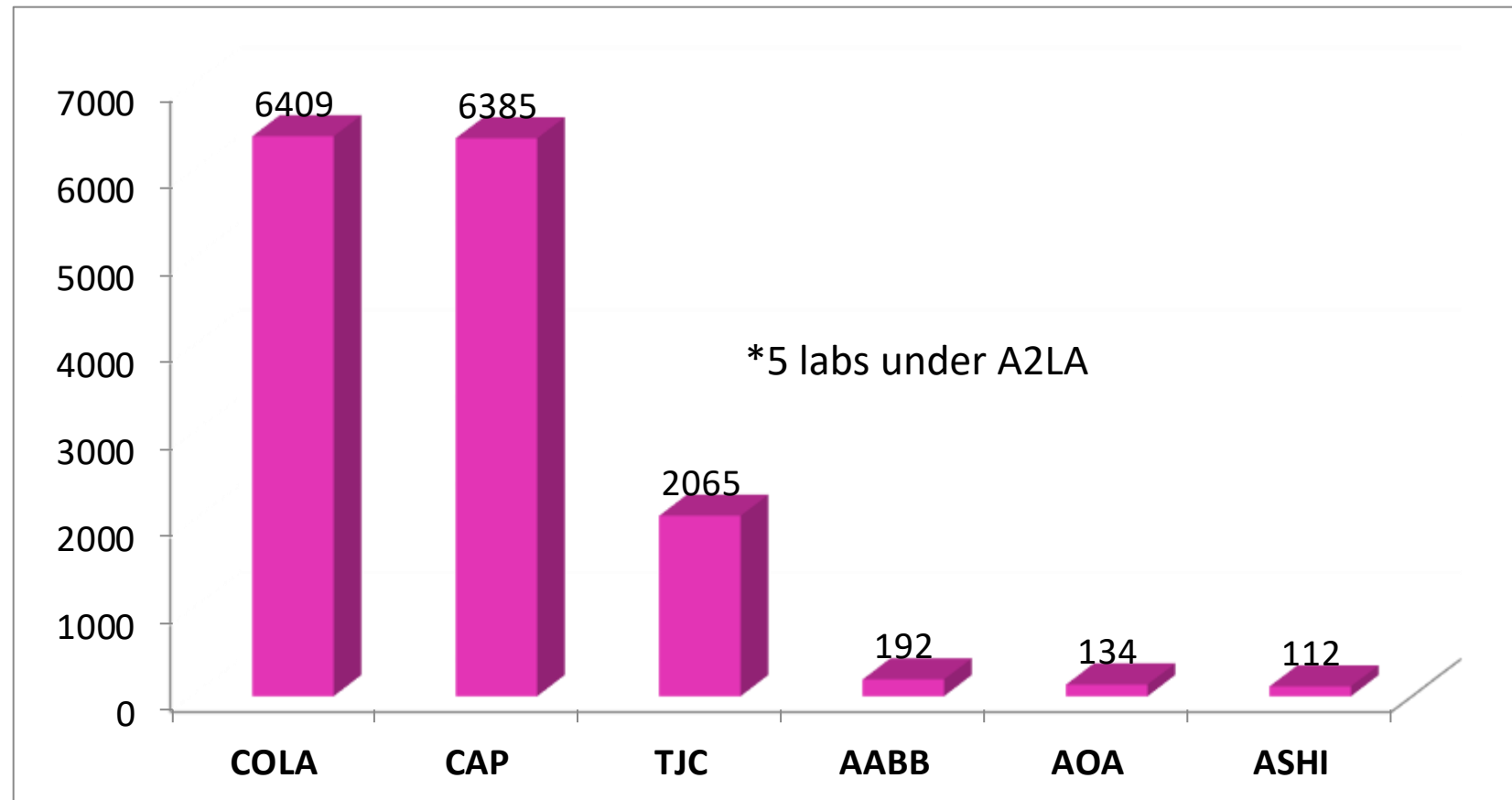
<b><u>Exempt</u></b>	<b><u>9,412</u></b>
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NY	5,245
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WA	4,167
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CMS data base 10/2018

# Certificate of Accreditation Laboratories



CMS data base 10/2018

# Top Ten Standard Level Deficiencies

Regulatory Subpart	Regulatory Cite	Deficiency	# all labs with deficiency	% all labs with deficiency
Analytic Systems (D5413) STANDARD	493.1252(b)	The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented.	804	4.8%
General Lab Systems (D5217) STANDARD	493.1236(c)(1)	At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I or this part.	726	4.3%
Personnel Competency Assessment (D5209) STANDARD	493.1235	As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.	691	4.1%
Analytic Systems (D5791) STANDARD	493.1289(a)	The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems	675	4.0%
Analytic Systems (D5403) STANDARD	493.1251(b)	The procedure manual must include the requirements for specimen acceptability, microscopic examination, step-by-step performance of the procedure, preparation of materials for testing, etc.	671	4.0%
Post Analytic Systems (D5805) STANDARD	493.1291(c)	The test report must indicate the following: for positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number, the name and address of the laboratory location where the test was performed, and other requirements specified in 493.1291(c).	589	3.5%
Procedure Manual (D5401) STANDARD	493.1251(a)	Written procedure manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel.	544	3.2%
Analytic Systems (D5429) STANDARD	493.1254(a)(1)	Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.	523	3.1%
Analytic Systems (D5417) STANDARD	493.1252(d)	Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of	521	3.1%
Verification of Performance Specifications (D5421) STANDARD	493.1253(b)(1)	Each laboratory that introduces an unmodified, FDA-cleared or approved test system must demonstrate that it can obtain performance specifications comparable to those established by the manufacturer.	478	2.8%

# Top Ten Condition Level Deficiencies

Regulatory Subpart	Regulatory Cite	Deficiency	# all labs with deficiency	% all labs with deficiency
Personnel Moderate Complexity (D6000) CONDITION	493.1403	The laboratory must have a director who meets the qualification requirements of 493.1405 and provides overall management and direction in accordance with 493.1407.	417	2.48%
Personnel High Complexity (D6076) CONDITION	493.1441	The laboratory must have a director who meets the qualification requirements of 493.1443 and provides overall management and direction in accordance with 493.1445.	266	1.58%
Analytic Systems (D5400) CONDITION	493.1250	Laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283.	236	1.41%
Personnel Moderate Complexity (D6063) CONDITION	493.1421	The laboratory must have sufficient number of individuals meeting the qualifications of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.	185	1.10%
Personnel Moderate Complexity (D6033) CONDITION	493.1409	The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 and provides technical oversight in accordance with 493.1413.	189	1.13%
Proficiency Testing (D2000) CONDITION	493.801	Each laboratory must enroll in a PT program that meets the criteria in subpart I and is approved by HHS. The laboratory must enroll for each specialty and subspecialty, and must test the samples in the same manner as patients' specimens.	179	1.07%
Proficiency Testing (D2016) CONDITION	493.803	Each laboratory performing nonwaived testing must successfully participate in a PT program approved by CMS as described in subpart I of this part for each specialty, subspecialty and analyte or test in which the laboratory is certified under CLIA.	117	0.70%
Personnel High Complexity (D6168) CONDITION	493.1487	The laboratory must have sufficient number of individuals who meet the qualification requirements concerning State licensure, if applicable, and the educational requirements for High complexity personnel as defined in 493.1489.	92	0.55%
Hematology Quality Systems (D5024) CONDITION	493.1215	If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269 and 493.1281 through 493.1299.	65	0.39%
Personnel High Complexity (D6108) CONDITION	493.1447	Have a technical supervisor who meets the qualification requirements as defined in 493.1449 and provides technical supervision in accordance with 493.1451.	59	0.35%

# Addressing the Top Ten Deficiencies

- **CLIA Brochures**
  - Review and update current brochures
  - Develop new brochures to address current policy and guidance
- **CLIA Webpage**
  - Update content, make more user friendly
  - Developing short, informational videos on policy, guidance
- **CLIA Booth**
  - Currently attend AACC, look into participation in other events such as HOSA, other professional meetings
- **Improve Surveyor Consistency**
  - Federal Monitoring Survey
  - State Agency Performance Review
  - Principles of Documentation
  - Virtual Training

# Federal Monitoring Surveys (FMS)

- The Regional Office has direct oversight of the State Agencies and the responsibility to validate the technical skills of surveyors in the performance of the CLIA Outcome-Oriented Survey Process and their adherence to CLIA policies and procedures
- CMS wide focus on use of LEAN tools and processes to improve
- FMS process revised/updated by work team consisting of RO representatives and CO staff. Revised process taken over a year to complete
- Training to occur November 2018
- New FMS to be implemented beginning in 2019



# Federal Monitoring Surveys (FMS)

- “Lean” revised FMS process includes:
  - Revised Standard Operating Procedures
  - “Fillable” worksheets (computer based vs paper based)
  - Standardized training on FMS process
  - Reports to SA manager and to CO

# Principles of Documentation

- A Central Office/Regional office team was assembled in 2017 to determine how to update the 2008 guidance, provide additional surveyor tools, and to develop surveyor training.
- The Central Office/Regional office team reviewed the 2008 guidance and determined that the Principles of Documentation guidance needed to be updated and clarified.
- This included updating examples for each of the eight principles. The updates also include clarification related to the uses of the different principles as well incorporating additional appendices (i.e., surveyor tools) with the guidance document.

# Principles of Documentation

- **The new appendices include, but are not limited to:**
  - Active versus Passive Voice
  - Composing a Deficiency Tag (D-Tag)
  - Checklist, Composing D-Tags
  - Additional examples for each principle
  - Cross Referencing
  - Multiple Citations under the Same Regulation
  - Frequently Asked Questions

## Lab Excellence Mailbox

Subject	1st Qtr 18	2nd Qtr 18	3rd Qtr 18
Data related emails	47%	40%	31%
Personnel/PSV	6%	9%	12%
Application for Certification	4%	12%	9%
Waived/POCT	6%	6%	5%
Uncategorized/Other	11%	9%	12%

# CLIA Outreach Program - Academic

- DCLIQ created the CLIA Outreach Program – Academic (COPA) in the summer of 2016.
- GOAL – Provide Medical Laboratory Science students the knowledge of CMS/CLIA and demonstrate the direct link between compliance with CLIA regulations and the production of high quality clinical laboratory testing. Promote Clinical Laboratory Science(CLS) as a vital and dynamic career for high school and post-secondary students.

# **COPA 2017 – 2018 Post Secondary events**

- 50 minute presentation – CLIA-101
- CLIA Regulations with real life examples of quality issues in clinical labs
- Insights to the variety and job advancement available in the clinical lab industry
- Website information

# COPA 2017 – 2018 High School events

- Attendance in April, 2018 at the USA Science and Engineering Festival in downtown DC. CLIA staff provided **177 HS/Post Secondary students** with information about a career in Clinical Lab Science.



# COPA Goals for the 2018 HOSA event

- Learn the structure/organization of HOSA-Future Health Professionals.
- Make face to face contacts with state chapter advisors; NJ, DE, WV, VA, PA and MD.
- Introduce our CLS High Schools programs
- Determine the best way to influence the leadership of this organization to incorporate and emphasize Clinical Laboratory Science in their career offerings.
- Make contacts with the post-secondary educators and professional organizations.



**HOSA Presentations reached approximately 140 students  
and the visitors to our exhibit were too many to count!**



# Contact Information

CLIA Website: [www.cms.hhs.gov/clia/](http://www.cms.hhs.gov/clia/)

CLIA Central Office: 410-786-3531

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